

### **REMARKS**

Claims 18-35 are pending in the application. Claims 1-17 were rejected under 35 U.S.C. §112, second paragraph, as described on page 2 of the Office Action. Claims 1-17 were rejected under the judicially created doctrine of obviousness-type double patenting as described on page 3 of the Office Action. Claims 1-17 were rejected under 35 U.S.C. §103 as described on page 4 of the Office Action. Claims 1-17 were rejected under 35 U.S.C. §102(b), or in the alternative, under 35 U.S.C. §103 as described on pages 4 and 5 of the Office Action. Claim 18 is the only independent claim.

The specification has been amended to place the application in correct idiomatic English and place the application in better U.S. form.

It is respectfully submitted that the outstanding rejections of claims 1-17 are moot, as the claims have been canceled.

It is respectfully submitted that claims 18-35 have been drafted in compliance with 35 U.S.C. §112, second paragraph.

It is respectfully submitted that claims 18-35 are patentable over claims 1-29 of U.S. Patent No. 6,497,842 within the meaning of the judicially created doctrine of obviousness-type double patenting for the following reasons.

In accordance with MPEP §804(II)(B)(1), a double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. §103" except that the patent principally underlying the double patenting rejection is not considered prior art.

35 U.S.C. § 103 authorizes the Patent and Trademark Office to refuse granting of a patent:

if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The underlined portion of the statute, coupled with the language in 35 U.S.C. § 102 that "a person shall be entitled to a patent unless" (emphasis added) places a heavy burden on any Examiner seeking to reject the claims of a patent application for obviousness, for it is the task of the patent Examiner to produce the factual basis for a rejection under 35 U.S.C. § 103. *In re Warner*, 379 F. 2d 1011, 154 USPQ 173 (CCPA 1967).

To safeguard the rights of patent Applicants and prevent perfunctory dismissal of patent claims, Congress and the Patent and Trademark Office have enacted statutes or rules and procedures which must be followed in the examination process.

35 U.S.C. § 132 mandates the Patent and Trademark Office, whenever rejecting any claim for a patent to:

notify the applicant thereof, stating the reasons for such rejection ... together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application.

Section 706.02(j) of the Manual of Patent Examining Procedure instructs:

[a]fter indicating that the rejection is under 35 U.S.C. § 103, the examiner should set forth in the Office Action (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate, (B) the difference or differences in the claim over the applied reference(s), (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and (D) **an explanation why one of skill in the art at the time the invention was made would have been motivated to make the proposed modification.** (Emphasis Added)

As a matter of Patent and Trademark Office practice, then, due process under 35 U.S.C. § 132 requires an Examiner, whenever rejecting a claim under 35 U.S.C. § 103, to include in his official action, (1) a statement regarding the features of the invention set forth in Applicants' claims; (2) a comparison of the claimed features of the invention with the closest prior art reference or references; (3) an explanation of why the differences between the features of an Applicants' claimed invention and the closest counterparts in the prior art are such that the claimed invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made, and (4) **sub-stantiation of that explanation with either evidence in the form of prior art references or sound scientific reasoning such that one may take official notice of it.** (Emphasis Added) See,

for example, *In re Hughes*, 345 F.2d 184, 145 USPQ 467 (CCPA 1965); *In re Soli*, 317 F.2d 941, 137 USPQ 797 (CCPA 1963). Indeed, whenever a claim is rejected under 35 U.S.C. § 103, the Examiner must "expressly make the three factual determinations required by Graham and consider objective evidence of obviousness before the legal conclusion of obviousness vel non is made." *Hybritech Inc. v. Monoclonal Antibodies, Inc.* 802 F2d 1367, 231 USPQ 91, 93 (Fed Cir. 1986)

In the present case, the rejection is under the judicially created doctrine of obviousness-type double patenting and the claims of the '842 patent show or describe inventions other than the claimed invention of the present application. On the record there are differences between the claims of the '842 patent and what is claimed. The Examiner has not explained why, despite the differences, the invention as a whole would have been obvious to one of ordinary skill at the time the invention was made. On the contrary, the Examiner merely states that "they are not patentably distinct from each other because they differ only in an obvious difference in scope." In the absence of an explanation supported by specific factual findings based on evidence or sound scientific reasoning, the rejection is merely conclusory in nature and is therefore improper.

In light of the above discussion, it is respectfully submitted that the Examiner has failed to establish a *prima facie* case of obviousness within the meaning of the judicially created doctrine of obviousness-type double patenting. For at least this reason, it is respectfully submitted that claims 18-35 are patentable over claims 1-29 of the '842 patent within the meaning of a judicially created doctrine of obviousness-type double patenting.

Nevertheless, it is respectfully submitted that claims 1-29 of the '842 reference fail to recite or suggest that the "liquid-impermeable sheet material does not cover said top surface of said first end region or said top surface of said second end region," as required in newly added independent claim 18. For this additional reason it is respectfully submitted that claims 18-35 are patentable over claims 1-29 of the '842 reference within the meaning of the judicially created doctrine of obviousness-type double patenting.

It is respectfully submitted that claims 1-35 are patentable over the remaining cited prior art of record for the following reasons.

The present invention relates to a chromatography measuring device for qualitatively or quantitatively measuring a substance to be tested. In accordance with one aspect of the present invention, a liquid-impermeable sheet material adherently covers a chromatographic test strip such that a top surface of a first end region and a top surface of a second end region of the chromatographic test strip is not covered by the liquid-impermeable sheet material. Accordingly, an applied liquid sample is operable to permeate in the chromatography downstream direction by a capillary phenomenon, and moisture evaporation is not produced in the region adherently covered with the liquid-impermeable sheet material. When the liquid sample reaches to an open part, moisture evaporates from the sample and the sample is dried. Further, the liquid which is held in a sample application part does not flow back but is developed in the chromatographic downstream direction. Therefore, the liquid and a marker reagent flowing for a predetermined time period can flow at uniform concentrations, whereby correct chromatography measuring can be performed.

Newly added independent claim 18, drawn to a chromatography measuring device comprises, *inter alia*, a chromatographic test strip, and a liquid-impermeable sheet material. More specifically, the chromatographic test strip of claim 18 is required to have "a first end region on a chromatographic upstream side operable to receive an application of a sample and a second end region on a chromatographic downstream side with respect to permeation of the sample." Further, the liquid-impermeable sheet material of claim 18 is required to be "adherently covering said chromatographic test strip." Still further, claim 18 requires that the first end region has a top surface, the second end region has a top surface and requires that the **"liquid-impermeable sheet material does not cover said top surface of said first end region or said top surface of said second end region."**

It is respectfully submitted that neither Nakaya, Mochizuki, or Takahashi, either singly or in combination, teaches the above-identified limitations.

In Nakaya, a protective laminate is pasted on a chromatography strip except for at least one region (detecting region) of the chromatography strip, and a space is formed on the top surface and/or the bottom surface of at least a part of the coloring region of the chromatography strip, thereby avoiding nonuniformity on the coloring region of the capillary flow of the sample liquid in

the chromatography strip. Nakaya fails to teach a liquid-impermeable sheet material that does not cover a top surface of a first end region or a top surface of a second end region as required in newly added claim 18.

Mochizuki and Takahashi fails to teach the shortcomings of Nakaya such that a combination of the teachings of Nakaya, Mochizuki and Takahashi would teach that which is required in claim 18.

The inspection body of Mochizuki comprises a chromatographic test strip between two moisture impermeable plastic films or thin plates. Mochizuki further discloses providing an upstream opening for pouring a sample to be tested and a downstream air vent opening for a member for absorbing. The reference further discloses bonding the films or plates so that an air flowing clearance is formed between the member for adding the sample to be tested and the member for absorbing the sample. The member for adding the sample to be tested and the member for absorbing the sample face one another at both ends of a film carrier for chromatographic development. Similar to Nakaya, as discussed above, Mochizuki fails to teach a liquid-impermeable sheet material that does not cover a top surface of a first end region or a top surface of a second end region as required in newly added claim 18.

Takahashi discloses an analyzer comprising a test strip covered with a liquid impermeable sheet having an opening part **only in the sample addition part at the upstream**. Accordingly, similar to both Nakaya and Mochizuki, Takahashi fails to teach a liquid-impermeable sheet material that does not cover a top surface of a first end region or a top surface of a second end region as required in newly added claim 18.

As described above, the present application has no need to provide a water absorption part which absorbs the sample in the chromatographic downstream direction of the chromatography specimen because the region in the chromatographic downstream direction of the chromatography specimen is not covered with a liquid-impermeable sheet material, thereby reducing the structural members and simplifying the process for generating a specimen. On the contrary, Nakaya, Mochizuki and Takahashi do not have such a construction. Thus, the present invention is different from each of Nakaya, Mochizuki and Takahashi in the construction and effect.

Because neither Nakaya, Mochizuki and Takahashi teach a liquid-impermeable sheet material that does not cover a top surface of a first end region or a top surface of a second end region as required in newly added claim 18, it is respectfully submitted that a combination of Nakaya, Mochizuki and Takahashi additionally fails to teach a liquid-impermeable sheet material that does not cover a top surface of a first end region or a top surface of a second end region as required in newly added claim 18.

In light of the above discussion, it is respectfully submitted that claim 18 is patentable over the combination of Nakaya, Mochizuki and Takahashi within the meaning of 35 U.S.C. § 103. Further as claims 19-35 are dependent upon claim 18, and therefore include all the limitations thereof, it is respectfully submitted that claims 19-35 are additionally patentable over the combination of Nakaya, Mochizuki and Takahashi within the meaning of 35 U.S.C. § 103.

In view of the above amendments and remarks, it is submitted that the present application is now in condition for allowance, and the Examiner is requested to pass the case to issue. If the Examiner should have any comments or suggestions to help speed the prosecution of this application, the Examiner is requested to contact Applicants' undersigned representative.

Respectfully submitted,

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